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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/623,108	07/18/2003	Ken-Shwo Dai	U 014726-8	4088

7590

03/01/2006

Ladas & Parry
26 West 61st Street
New York, NY 10023

EXAMINER

SANG, HONG

ART UNIT	PAPER NUMBER
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1643

DATE MAILED: 03/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/623,108	Applicant(s) DAI, KEN-SHWO	
	Examiner Hong Sang	Art Unit 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 and 32-34 is/are pending in the application.
- 4a) Of the above claim(s) 1-3, 5, 6, 8, 12-29 and 32-34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4, 7 and 9-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>11/14/03 & 2/9/04</u> . | 6) <input checked="" type="checkbox"/> Other: <u>Exhibits A&B</u> . |

DETAILED ACTION

RE: Dai

1. Applicant's election of Group II (claims 4-11) and the nucleic acid of SEQ ID NO. 5 in the reply filed on 12/19/2005 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
2. The information disclosure statements (IDS) filed on 11/14/03 and 2/9/04 have been considered. Signed copies are attached hereto.
3. Claims 1-29 and 32-34 are pending. Claims 30 and 31 are cancelled. Claims 1-3, 5, 6, 8, 12-29 and 32-34 are withdrawn from further consideration as being drawn to non-elected inventions.
4. Claims 4, 7 and 9-11 are under examination.

Specification

5. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

The abstract of the instant disclosure is objected to because it contains three paragraphs. Correction is required. See MPEP § 608.01(b).

Claim Objections

6. Claims 4, 7 and 9-11 are objected to as they contain non-elected inventions, i.e. SEQ ID NOS 1, 3 and 7.

Claim Rejections - 35 USC § 112, 1st paragraph

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 4, 7 and 9-11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

This rejection is made because the sole utility of the claimed nucleic acids asserted by the specification is for diagnosing cancer. However using the claimed nucleic acids to diagnose a cancer is not enabled by the instant specification for the reasons below.

Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 USC 112, first paragraph, have been described by the

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court in *In re Wands*, 8 USPQ2d 1400 (CA FC 1988). *Wands* states at page 1404,

"Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in *Ex parte Forman*. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims."

The nature of the invention

The claims are drawn to an isolated nucleic acid comprising a nucleotide sequence of SEQ ID NO. 5 and fragments thereof, a vector, a host cell and a method of producing an isolated polypeptide comprising SEQ ID NOS 2 and 4, and fragments thereof using the host cell.

The invention is in a class of invention, which the CAFC has characterized as "the unpredictable arts such as chemistry and biology." *Mycogen Plant Sci., Inc. v. Monsanto Co.*, 243 F.3d 1316, 1330 (Fed. Cir. 2001).

The breadth of the claims

The claims encompass SEQ ID NO. 5 and any fragment of SEQ ID NO. 5 and a method of making any fragments of SEQ ID NOS 2 and 4.

The state of the prior art and the predictability or lack thereof in the art:

The art teaches that there are many parameters that need to be evaluated prior to using gene expression as a diagnosis marker for a disease. Furthermore, the art teaches that the parameters that need to be addressed in order to conduct a study on

modulating gene expression yield gaps in information that are needed to complete a thorough screening of gene expression effects.

Shalon et al. (US 2001/0051344 A1, Dec 13, 2001) teach that due to variations in genetic make-up of unrelated individuals in a heterogeneous society, differences in the expression of a gene between any two individuals may or may not be significant (see page 10, paragraph 0155). Shalon et al. further teach that the larger the number of individuals tested, the more significant the remaining differences in gene expression become and samples from at least 5 and preferably 20-50 different test individuals are assayed to obtain statistically meaningful data showing a statistical elevation or reduction in report levels when compared to control levels (see page 10, paragraph 0156). Shalon et al. teach that the test average pattern is compared with a control average pattern on a microarray to identify test genes which show significantly, typically at least 2 fold and up to 100 fold or more, increase or decrease in gene expression level with respect to control levels for the same gene (see page 10, paragraph 0158). Kroese et al. (Genetics in Medicine, 2004, 6: 475-480) teach genetic tests are heterogeneous in nature and the exact characteristics of a particular genetic test to be evaluated must be tightly defined. Kroese et al. teach that a particular genetic condition may be caused by more than one gene and these variations may be due to deletions and insertions not detected by routine sequence methods (see page 476, 2nd column, last paragraph). Kroese et al. teach that genetic test is shorthand to describe a test to detect a particular genetic variant for a particular disease in a particular population and for a particular purpose and that it should not be assumed that once the characteristics of a genetic test

are evaluated for one of these reasons that the evaluation will hold or be useful for other purposes and all measures of the test performance should be presented with their 95% confidence intervals (see page 477, 1st column, 1st and 2nd full paragraph). Kroese et al. teach that the limitations of our genetic knowledge and technical abilities means that for the moment there are likely to be gaps in the information needed to complete a thorough evaluation of many genetic tests (see page 479, 2nd column, last paragraph). Additional art reveals that most gene association studies are typically wrong. Lucentini (The Scientist, 2004, Vol 18, page 20) teach that it strikingly common for follow-up studies to find gene-disease associations wrong (see page 2, 1st paragraph). Lucentini teaches that two recent studies found that typically when a finding is first published linking a given gene to a complex disease there is only roughly a one-third chance that the study will reliably confirm the finding (see page 2, 3rd paragraph). Lucentini teaches that bigger sample sizes and more family-based studies, along with revising statistical method, should be included in the gene association studies (see page 3, 2nd paragraph).

There is a large body of knowledge in the prior art related to polymorphisms in general, and their association with diseases or disease states, as well as drug or therapeutic response. However, the art is highly unpredictable with regard to the functionality of polymorphic sites in genomic DNA. After a screening assay identifies polymorphisms, it is unpredictable whether any such polymorphisms would be associated with any phenotypic trait, such as a disease state, a physiological state, or drug metabolism or response. For example, Hacker et al. teaches that they were

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unable to confirm an association between a gene polymorphism and ulcerative colitis in a case where prior studies suggested such a relationship would exist since the relationship had been identified in a different population (Gut, 1997, 40: 623-627). Even in cases where an association between a particular gene and a disease state is known to exist, such as with the LPL gene and heart disease risk or the p-globin gene and sickle cell anemia, researchers have found that when using SNP (single nucleotide polymorphism analysis) it was difficult to associate SNPs with disease states or to even identify key genes as being associated with disease (Pennisi, Science, 1998, 281(5384): 1787-1789). Further, in some cases where multiple polymorphisms were identified in a gene, some of these were demonstrated to be disease associated and some were not. For example, Blumenfeld et al. (WO 99/52942) disclose a number of polymorphisms in the FLAP gene. While Blumenfeld et al. were able to demonstrate that some of these polymorphisms are associated with patients having asthma, Blumenfeld et al. found that some of these polymorphisms are not (see Fig. 3). For example, the marker 10-35/390 was demonstrated to be associated with asthma, with a p value of 0.00229, while the marker 10-33/327 was determined not to have a statistical association with asthma ($p=0.294$).

Based on the data presented in the specification and the art teachings, it is unpredictable to correlate SEQ ID NO. 5 and its fragments to any cancer.

Quantity of experimentation

Based on the unpredictability of the art, the quantity of experimentation in this area is extremely large since it would require significant study to determine that the SEQ ID NO.5 and its fragments are in fact capable of diagnosing cancer.

Working examples:

The specification teaches analysis of human lung EST databases (see Example on page 20). The specification teaches how to isolate these cDNA clones (see example on page 20). While the specification teaches a general guideline for In Silico Tissue Distribution analysis (see page 22), there is no data indicating that there is a statistically significant difference between cancer and normal tissues regarding the existence of SEQ ID NO.5 and its fragments.

Guidance in the specification

The specification provides information that the SEQ ID NO.5 is found in many tumor cDNA libraries (see page 10, lines 1-3), and based on these findings, the specification asserts that SEQ ID NO. 5 and its fragments are important cancer markers. However, the specification fails to provide the evidence that the SEQ ID NO. 5 and its fragments indeed only exist in cancers not in normal tissues. There is no statistic study to indicate to one skilled in the art that the SEQ ID NO. 5 and its fragments are indeed capable of diagnosing cancer.

Moreover, even if the SEQ ID NO. 5 could be used to diagnose a cancer, not all fragments can be used to diagnose cancer or to detect SEQ ID NO.5. A fragment encompasses a nucleic acid as small as three residues. Such small fragments will

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hybridize to almost any nucleic acids, and therefore would not be useful for detecting SEQ ID NO.5 or diagnosing cancer. Even big fragments can hybridize to other nucleic acids. Therefore, one skilled in the art would not know how to use these fragments.

Level of skill in the art

The level of the skill in the art is deemed to be high

Conclusion:

Thus given the broad claims in an art whose nature is identified as unpredictable, the unpredictability of the art, the large quantity of research required to define these unpredictable variables, the lack of guidance provided in the specification, the absence of a working example which addresses the statistic difference between cancer and normal tissue regarding the existence of SEQ ID NO. 5 and its fragments and the negative teachings in the prior art balanced only against the high skill level in the art, it is the position of the examiner that it would require undue experimentation for one of skill in the art to perform the method of the claim as broadly written.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

10. Claim 4, 7 and 9-11 are rejected under 35 U.S.C. 102(b) as being anticipated
Rosen et al. (US20020055627A1, 5/9/2002).

Claims 4, 7 and 9-11 are drawn to an isolated nucleic acid comprising a nucleotide sequence selected from the group consisting of SEQ ID NO.5, and fragments thereof, wherein the fragment comprises nucleotides 1186 to 1236 of SEQ ID NO.5, an expression vector comprising SEQ ID NO.5 and fragments thereof, a host cell transformed with said expression vector and a method of producing an isolated polypeptide comprising an amino acid sequence selected from the group consisting of SEQ ID NOS 2 and 4, and fragments thereof, which comprises (1) culturing said host cell under a condition suitable for the expression of the polypeptide; and (2) recovering the polypeptide from the host cell culture.

Rosen et al. teach an isolated nucleic acid (SEQ ID NO. 668), an expression vector, a host cell and a recombinant method of producing the polypeptide using a host cell (see paragraph [0001], and claims 7, 10 and 15). The SEQ ID NO. 668 of Rosen et al. comprises nucleotides 1186 to 1236 of the instant SEQ ID NO.5 (see sequence alignment Exhibit A). The instant claims are drawn to an isolated nucleic acid comprising a nucleic acid sequence selected from the group consisting of SEQ ID NO.

5, and fragments thereof, therefore, the claims encompass an isolated nucleic acid comprising fragments of SEQ ID NO.5. Because the claims using the term “comprising” which is an open language, SEQ ID NO. 668 of Rosen et al., which comprises 1186-1236 residues of SEQ ID NO.5, reads on the instant nucleic acids.

11. Claim 4, 7 and 9-11 are rejected under 35 U.S.C. 102(e) as being anticipated Rosen et al. (US 2002/0147140A1, 10/10/2002, effective filing date: 1/17/2001).

The interpretation of claims 4, 7 and 9-11 is set forth above (see paragraph 10 above).

Rosen et al. teach an isolated nucleic acid (SEQ ID NO. 3351), an expression vector, a host cell and a recombinant method of producing the polypeptide using a host cell (see claims 1, 7, 10 and 15). The SEQ ID NO. 3351 of Rosen et al. comprises nucleotides 1186 to 1236 of the instant SEQ ID NO.5 (see sequence alignment Exhibit B). The instant claims are drawn to an isolated nucleic acid comprising a nucleic acid sequence selected from the group consisting of SEQ ID NO. 5, and fragments thereof, therefore, the claims encompass an isolated nucleic acid comprising fragments of SEQ ID NO.5. Because the claims using the term “comprising” which is an open language, SEQ ID NO. 3351 of Rosen et al., which comprises 1186-1236 residues of SEQ ID NO.5, reads on the instant nucleic acids.

Conclusion

12. No claims are allowed.


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13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hong Sang whose telephone number is (571) 272 8145. The examiner can normally be reached on 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Hong Sang
Art Unit 1643
Feb. 15, 2006



LARRY R. HELMS, PH.D.
SUPERVISORY PATENT EXAMINER

Sequence 103735, A
Sequence 97357, A
Sequence 97358, A
Sequence 97359, A
Sequence 103733, A
Sequence 103734, A
Sequence 103735, A
Sequence 10475, A
Sequence 10475, A
Sequence 173660, A
Sequence 2115, Ap
Sequence 255989, A
Sequence 255989, A
Sequence 132, Ap
Sequence 28, Appl
Sequence 5, Appl
Sequence 668, Ap
Sequence 4981, Ap
Sequence 6991, Ap
Sequence 6778, Ap
Sequence 33612, A
Sequence 7, Appl

ALIGNMENTS

RESULT 1
US-09-925-299-668 Application US/09925299
Sequence 668, Application US/09925299
Patent No. US2002005527A1
GENERAL INFORMATION:
APPLICANT: Rosen et al.
TITLE OF INVENTION: Nucleic Acids, Proteins and Antibodies
FILE REFERENCE: PA102
CURRENT APPLICATION NUMBER: US/09/925,299
PRIOR FILING DATE: 2001-08-10
PRIOR FILING DATE: 2000-03-08
PRIOR FILING DATE: 1999-03-12
NUMBER OF SEQ ID NOS: 1556
SOFTWARE: Patentin Ver. 2.0
SEQ ID NO 668
LENGTH: 365
TYPE: DNA
ORGANISM: Homo sapiens
FEATURE:
NAME/KEY: misc_feature
LOCATION: (8)
OTHER INFORMATION: n equals a,t,g, or c
NAME/KEY: misc_feature
LOCATION: (172)
OTHER INFORMATION: n equals a,t,g, or c
NAME/KEY: misc_feature
LOCATION: (239)
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NAME/KEY: misc_feature
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OTHER INFORMATION: n equals a,t,g, or c
US-09-925-299-668

LOCATION: (358)
OTHER INFORMATION: n equals a,t,g, or c
NAME/KEY: misc_feature
LOCATION: (362)
OTHER INFORMATION: n equals a,t,g, or c
US-09-925-299-668
Query Match
Best Local Similarity 100.0%; Score 51; DB 3; Length 365;
Matches 51; Conservative 0; Mismatches 0; Indels 0; Gaps 0;
Qy 1 ACAGACTGGCAAGAGGCAAGAGTCACTGAGGCGCTCTGTCACCCAGGA 51
Db 32 ACAGACTGGCAAGAGGCAAGAGTCACTGAGGCGCTCTGTCACCCAGGA 82
RESULT 2
US-09-925-299-668
Sequence 668, Application US/09925299
Publication No. US20030040617A9
GENERAL INFORMATION:
APPLICANT: Rosen et al.
TITLE OF INVENTION: Nucleic Acids, Proteins and Antibodies
FILE REFERENCE: PA102
CURRENT APPLICATION NUMBER: US/09/925,299
PRIOR FILING DATE: 2001-08-10
PRIOR FILING DATE: 2000-03-08
PRIOR FILING DATE: 1999-03-12
NUMBER OF SEQ ID NOS: 1556
SOFTWARE: Patentin Ver. 2.0
SEQ ID NO 668
LENGTH: 365
TYPE: DNA
ORGANISM: Homo sapiens
FEATURE:
NAME/KEY: misc_feature
LOCATION: (8)
OTHER INFORMATION: n equals a,t,g, or c
NAME/KEY: misc_feature
LOCATION: (172)
OTHER INFORMATION: n equals a,t,g, or c
NAME/KEY: misc_feature
LOCATION: (239)
OTHER INFORMATION: n equals a,t,g, or c
NAME/KEY: misc_feature
LOCATION: (243)
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LOCATION: (358)
OTHER INFORMATION: n equals a,t,g, or c
NAME/KEY: misc_feature
LOCATION: (362)
OTHER INFORMATION: n equals a,t,g, or c
US-09-925-299-668
Query Match
Best Local Similarity 100.0%; Score 51; DB 3; Length 365;
Matches 51; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

RESULT 7
 US-09-816-095-3
 ; Sequence 3, Application US/09816095
 ; Patent No. US20020137164A1
 ; GENERAL INFORMATION:
 ; APPLICANT: GAN, Weiniu
 ; TITLE OF INVENTION: ISOLATED HUMAN
 ; TITLE OF INVENTION: ACID MOLECULE
 ; TITLE OF INVENTION: THEROP
 ; FILE REFERENCE: CL001147
 ; CURRENT APPLICATION NUMBER: US/09/